

terms of demographic data, nor did the objective or subjective parameters reveal any significant differences between the groups. Side effects (numbness, headache) were documented by two subjects receiving hay bath.

Conclusion: When using the hay bath, potential side effects must be taken into account. In view of the increasing use of Graminis flos in phytobalneotherapy, investigations involving large groups of patients with defined illnesses are needed in order definitively to establish the effectiveness and risks of the hay bath.

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Phytotherapy in inflammatory bowel diseases (IBD)

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Phytotherapy is one of the major fields in “Klassischer Naturheilkunde” in Germany and it is the most frequented one. In 2003 more than 2 billion dollar was spent for over-the-counter herbal treatment.

In Germany more than 300,000 patients suffer from IBD, mainly Crohn’s disease and ulcerative colitis.

In IBD every other patient has personal experience with CAM. Almost 44% of these patients had experience in the field of Herbal therapy, mainly as an adjunct to conventional therapy in an integrated medical treatment approach.

One way to implement herbs in the treatment is self-help strategies such as tea. Moreover, there are various herbal preparations with promising results in the treatment of IBD. In Germany there is major interest in the herbs isphagula, frankinsence, myrrh and camomile for the treatment of IBD. Moreover, ginger, curcumin, tormentill, wormworth and green tea have shown first promising results.

The different herbs will be introduced and existing data or ongoing research will be presented.

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Potential confounders in studies of complementary alternative medicine: Which study design?

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The design of a scientific study should be appropriate to answer the study question but independent of the theory

which generated the study question. Different study designs will be needed to answer questions related to diagnosis, therapy or prevention but may not be needed to investigate different treatments founded by different theories.

Aim: Using the example of treatment-related questions we discuss the applicability of 12 questions [Usability of Scientific Publications (USP) Questionnaire; manuscript submitted] to studies of complementary alternative medicine.

Methods: Q1 Was the aim of the study clearly stated? Q2 Was the design appropriate to answer study question? Q3 Can the design of the study be used in a confirmatory study? Q4 Were the risk profiles of the study populations similar? Q5 Was the allocation of patients to study groups concealed? Q6 Were doctors and patients continuously blinded? Q7 Was the follow up long enough to detect the defined endpoint? Q8 Were all patients included in reported results? Q9 Were adequate statistics applied? Q10 Were the results influenced by conflicting interests? Q11 Is the validity of report acceptable? Q12 Is the described effect clinically relevant?

Result: The questions Q1, Q2, Q7–Q10 and Q12 can be answered without specific instruction. Possible answers to the other questions are: Q3 The designs of some studies are ambiguous and not clear enough to be used in a confirmatory study. Q4 The risks of harm may be imbalanced among the investigated groups. Imbalanced means that most of the risk factors indicate a marginally higher risk of harm in one of the investigated groups. Q5 The answer to this question is “no” if the allocation to a particular treatment group can be predicted. Q6 In some studies doctors and/or patients can identify rather fast to which treatment a particular patient is allocated. Q11 This question should be answered by a group of advocates and skeptics of the tested treatment.

Conclusion: It is not possible to recommend a “one fits all” study design but the criteria can be specified which influence the validity of the study results. Two interesting aspects have to be discussed in more detail, the role of randomization and the threshold of validity. Increasing evidence indicates that both aspects may be more a societal than a scientific problem.

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How should we take into consideration experimental data about the interaction of CAM and antitumoral medicacian therapeutics when planning an individual therapy or a study?

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